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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,583	02/05/2001	Karl-Hermann Schlingensiepen	P66141US0	7033

136 7590 12/06/2006

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,583	Applicant(s) SCHLINGENSIEPEN ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 9-21-06.

Claims 1, 2 and 6-11 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claim 6 and SEQ ID Nos. other than elected SEQ ID Nos. 7, 9 and 14, drawn to an invention nonelected with traverse in the elections filed 1-31-06 and 9-21-06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's election with traverse of SEQ ID Nos. 7, 9 and 14 in the replies filed on 1-31-06 and 9-21-06 is acknowledged. The traversal is on the ground(s) that the requisite number of sequences examined in an application as set forth in the MPEP at 803.04 is ten. This is not found persuasive because the MPEP at 803.04 set forth the suggested maximum number of sequences to be searched in a single application to be ten. It did not set forth a requisite number of sequences to be searched in a single application. Furthermore, at the time these suggested guidelines for restrictions were written, the data bases were not as extensive and so sequence searches were much less burdensome to perform, and so ten was often a reasonable amount of sequences to search. Since then, the data bases that must be searched for adequate examination of sequences have expanded tremendously (e.g. data continues to stream in from the

various genome projects). For these reasons, the restriction to three sequences is a reasonable number and, hence, the instant restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim 6 and SEQ ID Nos. other than SEQ ID Nos. 7, 9 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9-21-06.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 4-21-06.

The claims are drawn to a composition comprising at least one oligonucleotide inhibitor of an immune response selected from SEQ ID Nos. 1-213, and further comprising at least one stimulator positively effecting an immune response, which stimulator optionally enhances the synthesis and/or function of factors selected from GM-CSF, SCF, CSF, IFN, FLT-3-ligand, monocyte chemotactic proteins, IL-2, IL-4, IL-12 and/or IL-18, a virus, viral antigen, tumor or pathogenic antigen, or organ specific

antigens expressed in affected organs but not essential for the organism or fusion of dendritic and tumor cells.

Applicant's arguments filed 9-21-06 have been fully considered but they are not persuasive. Applicant argues that adequate written description has been provided for the very broad genus comprising the above mentioned stimulators positively effecting an immune response because the term "medicament" has been removed from the claims and the instantly claimed invention does not embrace treatments. Applicants are correct that the claims have been amended and treatment effects are not inherently encompassed by the instant claims. However, contrary to Applicant's assertions, the removal of the term "medicament" from the instant claims does not satisfy the written description requirement for the very broad genus of biological agents claimed.

The genus claimed encompasses any stimulator of the immune response that enhances the synthesis or function of any molecule that stimulates, enhances, up-regulates or positively regulates the immune response, including but not limited to molecules or agents that lead to the stimulation or enhancement of the synthesis or function of *GM-CSF, SCF, CSF, IFN, FLT-3-ligands, monocyte chemotactic proteins, IL-2, IL-4, IL-12 and/or IL-18, any virus or viral antigens, any tumor or pathogenic antigens, and any organ specific antigens expressed in affected organs but not essential for the organism or fusion of dendritic and tumor cells.* The myriad of molecules embraced by this genus is vast (thousands and thousands of species). The laundry list of agents provided in the instant disclosure does not provide adequate support for the expansive

genus of biological agents claimed. For these reasons, the instant written description rejection is maintained.

Claims 1, 2, 7, 8, 10 and 11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 12-15 of copending Application No. 10/984,919 for the reasons of record set forth in the Office action mailed 4-21-06.

No arguments have been made addressing this rejection.

Claims 1, 2, 7, 8, 10 and 11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 6 of copending Application No. 10/220,033 for the reasons of record set forth in the Office action mailed 4-21-06.

No arguments have been made addressing this rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1635

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1635

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
12-4-06

J3
TC1600
JANE ZARA, PH.D.
PRIMARY EXAMINER